IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
March 23, 2009

Charles R. Fulbruge III
Clerk

No. 08-20397

UNITED STATES OF AMERICA

Plaintiff - Appellee

v.

GAYLE ROTHENBERG

Defendant - Appellant

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:07CR100

Before SMITH, OWEN, and HAYNES, Circuit Judges.

HAYNES, Circuit Judge:[*]

Appellant, Gayle Rothenberg, appeals her conviction on twelve counts of mail fraud, misbranding of a drug, and making a false statement. For the reasons set forth below, we VACATE her sentence, REVERSE her conviction, and REMAND for a new trial.

[*] Pursuant to 5TH CIR. R. 47.5, the Court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

I. Facts

Dr. Rothenberg was a licensed Texas physician who, during the last decade, operated an "aesthetic medicine" office in Houston, Texas. One of the services she offered was Botox injections. Botox is the brand name for a drug derived from botulinum toxin type A ("BTA"), manufactured by Allergan Corporation ("Allergan"). It is undisputed that Botox is the only form of BTA approved by the Food and Drug Administration ("FDA"). During several months in 2004, Dr. Rothenberg began using a form of BTA that is not FDA-approved and that was manufactured by an Arizona company called Toxin Research International, Inc. ("TRI"). The Government alleges that Dr. Rothenberg, with intent to defraud, told patients that she was using Botox, when in fact, she was using the cheaper, unapproved TRI BTA. Dr. Rothenberg was charged with thirteen counts that included conspiracy to misbrand and commit mail fraud, substantive mail fraud and misbranding counts, and one count of making a false statement (to the investigating FDA agent). After her first trial ended in a hung jury, Dr. Rothenberg was retried and found guilty on all counts except for one of the mail fraud counts. Dr. Rothenberg now appeals, challenging several of the district court's evidentiary rulings as well as the jury charge.

II. Standard of Review

This Court reviews the district court's evidentiary rulings, when properly objected to, under an abuse of discretion standard. *United States v. Garcia*, 530 F.3d 348, 351 (5th Cir. 2008). "'A trial court abuses its discretion when its ruling is based on an erroneous review of the law or a clearly erroneous assessment of the evidence.'" *Id.* (quoting *United States v. Yanez Sosa*, 513 F.3d 194, 200 (5th Cir. 2008)). This Court heightens its review of evidentiary rulings in criminal trials. *Id.* An abuse of discretion in admitting or excluding evidence is subject to a harmless error review. *Id.* A properly preserved challenge to jury

instructions is also reviewed under an abuse of discretion standard. *United States v. Dien Duc Huynh*, 246 F.3d 734, 738 (5th Cir. 2008).

III. Discussion

The essence of much of the Government's case against Dr. Rothenberg was that she represented that the TRI BTA was, in fact, Botox-branded BTA and that she did so with the intent to defraud her patients. Much of the evidence Dr. Rothenberg challenges on this appeal was presented by the Government ostensibly to show Dr. Rothenberg's intent to defraud (which was relevant to all but one of the counts against her).

A. The Florida Incident

Patricia McDonald, a former employee of Dr. Rothenberg, testified, over vociferous objections, about reading an article discussing an incident in which "somebody in Florida had been hurt." She claimed that she brought this article to Dr. Rothenberg's attention and that Dr. Rothenberg decided not to use the TRI BTA as a result of their conversation. While somewhat confusing, the testimony from Ms. McDonald clearly implied that the BTA used in Florida came from the same company as that used by Dr. Rothenberg – TRI – when this is not the case. Also, the testimony is questionable because the Florida incident did not occur until November 2004; Dr. Rothenberg stopped using the TRI BTA in September 2004.[1] The district court refused to instruct the jury that the Florida incident did not involve TRI BTA or Dr. Rothenberg. The judge did give a limiting instruction that this testimony was not admitted for the truth of the matter asserted but instead to show Dr. Rothenberg's state of mind and intent.

[1] Allergan's pharmaceutical representative, Ashley Linn, confronted Dr. Rothenberg about her lack of Allergan orders in September 2004, threatening to report the doctor. Dr. Rothenberg immediately stopped ordering the TRI BTA, placed an Allergan order that day and began using the Allergan Botox after that time. The Government made no effort to prove that Dr. Rothenberg ever used the TRI BTA after September 2004, and, indeed, its various charts and analyses assumed the cessation of use in September.

The Government similarly argues to this Court that this evidence is relevant to Dr. Rothenberg's state of mind. Dr. Rothenberg contends this evidence is irrelevant; at the very least, she contends, any probative value is substantially outweighed by its prejudicial effect. *See* FED. R. EVID. 403; *United States v. Spletzer*, 535 F.2d 950, 955-56 (5th Cir. 1976).

"The admission into evidence of facts that do not concern the defendants, that are not inextricably intertwined with the overall criminal episode is reversible error if the admission prejudices the defendants." *United States v. Dillman*, 15 F.3d 384, 391 (5th Cir. 1994). We see little, if any, relevance in an article about patients Dr. Rothenberg did not treat, in a state in which she does not practice, concerning a substance from a source other than TRI, at a time after she stopped using the challenged TRI BTA substance. We further agree with Appellant that any probative value of this information is substantially outweighed by the prejudicial effect of telling the jury that people were hurt from this product and the confusion engendered by suggesting that it was the same product used by Dr. Rothenberg.[2] Despite calling a number of patients as witnesses and investigating the records of many more, the Government never proved that any patient of Dr. Rothenberg was harmed by the TRI BTA.

We conclude that the district court abused its discretion in admitting this evidence. It is unnecessary for us to determine whether this error by itself was sufficiently prejudicial to necessitate a new trial because we conclude that this error, coupled with the error discussed in the next section, definitely necessitates a new trial.

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[2] The error in admitting this evidence then led to the defense's having to respond to this evidence by attempting to show, through TRI's Chad Livdahl, that the substance in Florida was not the same as the TRI BTA. This testimony, in turn, became confused, further confusing the jury. While the Government contends that Dr. Rothenberg's counsel took pains to tie Mr. Livdahl to the Florida incident, it is clear that the questioning was designed to yield just the opposite result.

B. Chad Livdahl's Testimony

Chad Livdahl was the head of TRI. It is undisputed that he neither met nor spoke with Dr. Rothenberg. He also was not directly involved in shipping or selling any of the products Dr. Rothenberg bought from his company. In more than ninety pages of testimony elicited by the Government on direct, it is difficult to find any testimony that is both relevant and not cumulative. Instead, resplendent in prison garb,[3] Mr. Livdahl gave testimony that is replete with irrelevant, prejudicial and potentially confusing testimony. Examples of this irrelevant and prejudicial evidence include several pages of testimony about how Mr. Livdahl tested the TRI BTA by injecting it into guinea pigs until they died. He also tested it on himself. He testified about the FDA clinical trials process,[4] without any indication that he is an expert in or even knowledgeable about this process, which he admittedly did not utilize. He testified extensively about his own criminal conviction, which was highly prejudicial and irrelevant. Mr. Livdahl also testified about what someone "would be told" if they called TRI, but no evidence was presented by either side that Dr. Rothenberg ever called TRI or spoke to Mr. Livdahl. The few relevant answers he gave were cumulative of testimony by others more directly involved in the events in question.

The Government then heightened the prejudicial effect of this information by making references to it in closing argument, telling the jury to "realize how important it is to have oversight from the FDA, so you don't have some witch doctor like Mr. Livdahl concocting anything he wants and trying to distribute it

[3] That Mr. Livdahl testified while attired in prison garb only heightened the prejudicial effect of this testimony.

[4] Mr. Livdahl's testimony was not necessary to establish anything about the FDA processes, even if some were relevant. The Government called Dr. Mark Walton, the Senior Medical Policy Advisor for the FDA, on this subject.

throughout the United States." In its closing, the Government also made reference to the highly prejudicial testimony concerning guinea pig testing.

The Government contends that Mr. Livdahl's testimony was necessary to establish that the materials accompanying the TRI BTA were marked "for research only, not for human use." However, Mr. Livdahl had no personal knowledge about the actual boxes and invoices that were sent to Dr. Rothenberg. The Government laboriously went over TRI invoices with Dr. Rothenberg's office personnel, Patricia McDonald and Jana Metoyer, who read this language from these invoices and similar documents. Ms. Metoyer also testified to Dr. Rothenberg's possession of a Material Safety Data Sheet for the TRI BTA which contained the "not for human use" language. Randy Rakes, a pharmaceutical sales representative for another company, testified to seeing a bottle, as well as a TRI flyer, in Dr. Rothenberg's office with the "not for human use" language. The investigating agent, James Miller, also testified at length that Dr. Rothenberg admitted to seeing this "not for human use" language in the materials accompanying the TRI BTA. Finally, the defense conceded this point in its opening statement and never disputed that this language was contained in the TRI materials sent to Dr. Rothenberg.

We conclude that, overall, this irrelevant and cumulative evidence was misleading and confusing as well as highly prejudicial to Dr. Rothenberg. When combined with the irrelevant and prejudicial testimony about the Florida incident, these errors constitute harmful error and necessitate a new trial.[5] *See United States v. Riddle*, 103 F.3d 423, 434-35 (5th Cir. 1997).

[5] The Government contends that, because Dr. Rothenberg subpoenaed Mr. Livdahl for the first trial (that ended in a mistrial), she has somehow waived her objections to his irrelevant and prejudicial testimony elicited by the Government. To state this argument is to show its fallacy.

C. Standards of Care and Administrative Regulations

Mindful that there will be a retrial, we address the remaining points of error raised by Dr. Rothenberg. Dr. Rothenberg challenges the admission of evidence from the Director of Enforcement from the Texas Medical Board, Mari Robinson, and three physicians to the effect that Dr. Rothenberg violated several Texas administrative rules and laws governing doctors and failed to follow appropriate medical procedures. The district court gave the following limiting instruction in connection with the admission of this evidence: "Furthermore, if the defendant has violated a rule or regulation of the Texas State Board of Medical Examiners, or if her conduct has shown to have differed from that of other physicians under like or similar circumstances, such did not necessarily establish that she committed the separate and distinct criminal offenses charged in the indictment."

Dr. Rothenberg contends that the admission of this type of evidence violates *United States v. Christo*, 614 F.2d 486 (5th Cir. 1980). We disagree. As explained in *United States v. Ramos*, 537 F.3d 439, 459-60 (5th Cir. 2008), *cert. denied* (U.S. Mar. 23, 2009) (Nos. 08-755 & 08-756), the problem in *Christo* was that the civil standards were equated with the criminal standards. The district court's limiting instruction in this case made clear that the two are not the same. With appropriate limiting instructions, civil regulations and standards can sometimes be relevant to the question of intent. *See, e.g.*, *United States v. Brown*, 553 F.3d 768, 791-92 (5th Cir. 2008). Thus, we agree with the Government that civil regulations and standards, generally known to doctors practicing in the same or similar areas as Dr. Rothenberg, could bear upon her intent in connection with the TRI BTA. The question then becomes whether the actual evidence admitted was appropriate or strayed too far from that which is admissible.

Ms. Robinson testified about the rules and regulations governing Texas-licensed doctors. The district court allowed Robinson to testify about her understanding of how the Board interprets its rules, relying on our decision in *United States v. Griffin*, 324 F.3d 330, 347-48 (5th Cir. 2003), and the Seventh Circuit's decision in *United States v. Davis*, 471 F.3d 783, 788-89 (7th Cir. 2006). We agree with the Seventh Circuit that, in cases where it is relevant, an expert can opine about how a board charged with administering a regulation actually interprets that regulation, subject to the court's conducting an appropriate Rule 403 balancing. *See Davis*, 471 F.3d at 789. However, we note, as *Griffin* stated, that opinion testimony about "what the law is" or some expert's "understanding" about what the law means is impermissible. *See Griffin*, 324 F.3d at 348.

Having reviewed Ms. Robinson's testimony, we conclude that the district court carefully held her to the areas permitted by *Griffin* and *Davis*. We find no error in the admission of her testimony.

We cannot say the same about the three doctors called by the Government on this point – Drs. Kronberg, Hamilton and Bruce. None of these doctors were qualified as experts on Texas medical regulations. Indeed, Dr. Hamilton repeatedly disclaimed any real knowledge of such rules and regulations. The other two doctors stated that they were generally familiar with medical rules but provided no basis upon which to conclude that they were experts on the subject. Thus, their testimony about rules and regulations was improper.

Additionally, the doctors testified about whether *they* would use a drug on humans that was labeled "not for human use" and what *their* practice was in keeping records. The Government suggested that evidence about the standard of care would be relevant to Dr. Rothenberg's intent to the extent she deviated from it. While the standard of care for a doctor could, in some instances, be relevant in a criminal case (with proper limiting instructions), these doctors did

not testify about the standard of care. Instead, they testified what they did or would do.[6] Even in a civil malpractice case, that evidence is irrelevant. What a random doctor in Houston might do does not establish the standard of care for Dr. Rothenberg that then, in turn, can be probative of her intent. *See Whittley v. Heston*, 954 S.W.2d 119, 123 (Tex. App.–San Antonio 1997, no pet.) ("A testifying expert cannot establish the standard of care by simply stating the course of action he would have taken under the same or similar circumstances."). Further, in violation of *Griffin*, these doctors testified to their understanding of the law. *See Griffin*, 324 F.3d at 348. Admission of that testimony was error.

At oral argument, the Government stated that the doctors' testimony is relevant because Dr. Rothenberg claimed that she consulted with "colleagues" about the "not for human use" language and continued to use the TRI BTA after receiving reassurance from those "colleagues." No evidence indicated that Dr. Rothenberg claimed to have spoken to *these* three colleagues about this language. Tellingly, although all three testifying doctors were acquainted with Dr. Rothenberg, all denied having a conversation with Dr. Rothenberg about this language or whether she should use TRI BTA.[7] Randomly picking three doctors from the thousands who practice in this field to testify about what they would

[6] Dr. Kronberg received a mailing from TRI containing the "not for human use" language and indicated that such a warning would keep her from using the product. She also gave her "understanding" of Board rules and what the law requires. She also testified about how she keeps records. Dr. Hamilton indicated that he would not knowingly use a drug that is not FDA-approved. Dr. Bruce also got a flier from TRI and was concerned about the fact that it was not FDA-approved. She said that she would not use a product labeled "not for human use" on her patients. The closest she came to "standard of care" evidence was her testimony that it was "standard practice" to keep records regarding the lot numbers and related information for drugs administered to her patients.

[7] Dr. Hamilton stated that he had a conversation with Dr. Rothenberg after the FDA investigation in which she said that she had used a substitute product for Botox and made an "error in judgment." However, they did not discuss the "not for human use" language.

do cannot possibly bear on what Dr. Rothenberg was told by the "colleagues" with whom she allegedly spoke.[8]

Because of our resolution of other issues, we need not decide if the admission of the three doctors' testimony was harmful error. We trust that on remand, the improper questioning will not occur.

D. Other Issues

Dr. Rothenberg also challenges the district court's refusal to allow her expert to testify that the term "Botox" was used generically in articles and speeches in the 1980's. There is no showing that this generic use of "Botox" continues to the present or that Dr. Rothenberg was practicing in this area of medicine at that time or would have had any exposure to the articles or speeches in question in the 1980's. We agree with the district court that the testimony was irrelevant and find no error in the district court's ruling in this regard.

We also find no reversible error in the court's charge on good faith reliance on counsel because the instructions fairly and adequately covered this issue. *See United States v. St. Gelais*, 952 F.2d 90, 93 (5th Cir. 1992).

IV. Conclusion

For the forgoing reasons, we VACATE Rothenberg's sentence, REVERSE her conviction, and REMAND this case for a new trial consistent with this opinion.

[8] In opening statement, Dr. Rothenberg's attorney identified a Dr. Humble from California as the "colleague" Dr. Rothenberg consulted about the "not for human use" language.